

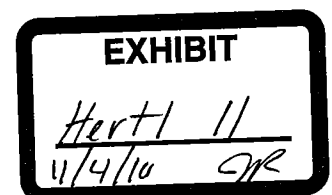
Reasons for change

- **To simplify Product/Project Management in HAES.**
- **To bring project management closer to technical sections by discipline.**
- **To improve interface with Global Regulatory Affairs.**
- **To facilitate the movement of key outputs from technical areas to the end-user with integration of technical and product information.**

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Project Management In HAES

JED to meet with Heads of other disciplines (Ecological Hazard, Dietary Exposure, Environmental Fate and Exposure) to monitor standards and to ensure consistency of Project Management across HAES.

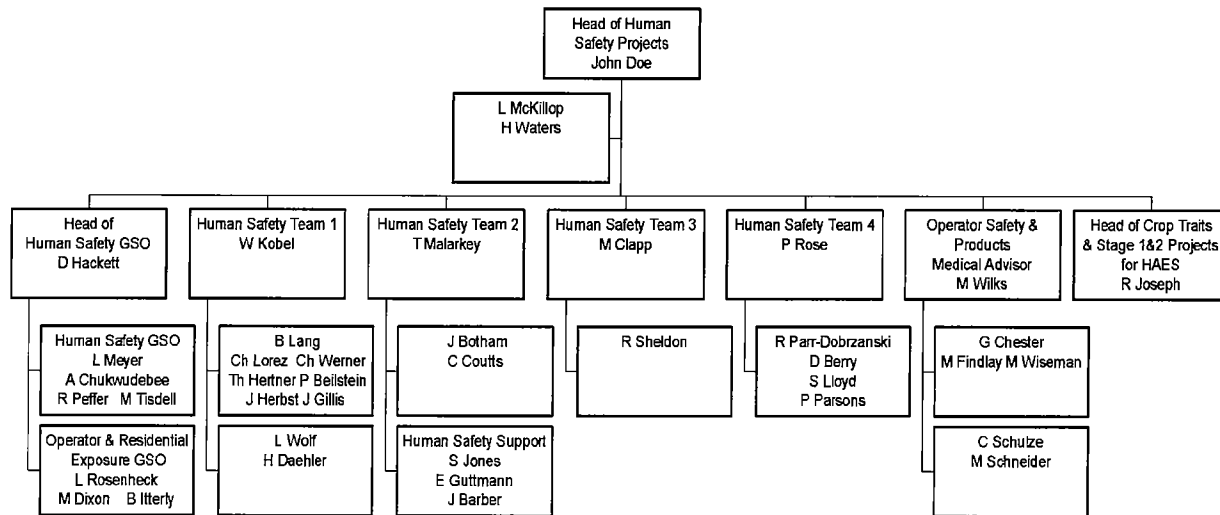


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Global Human Safety Projects Group



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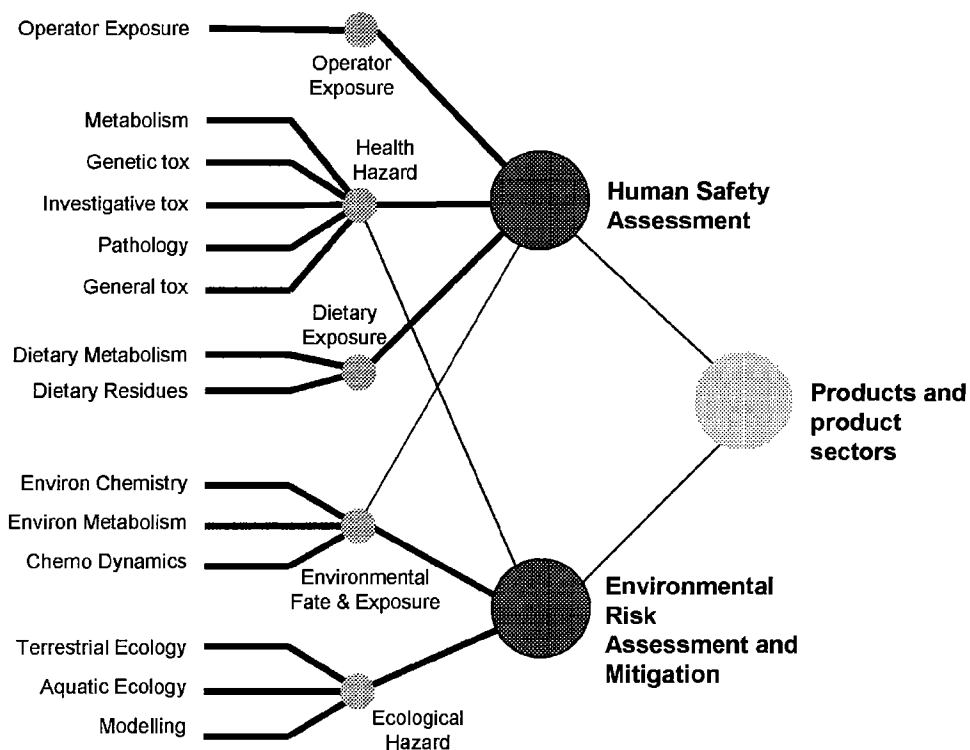
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HSP

- **4 Human safety teams: Each responsible for groups of products**
- **Each Product will be led Globally by one person (wherever they are located)**
- **2 teams responsible for operator and residential exposure (1 NAFTA, 1EU with Products Medical Advisor)**
- **1 team/1 person responsible across HAES for early product research and crop traits.**

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HAES Process Map



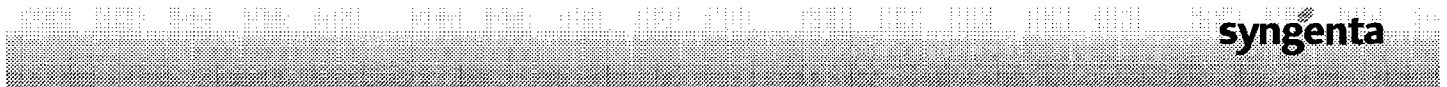
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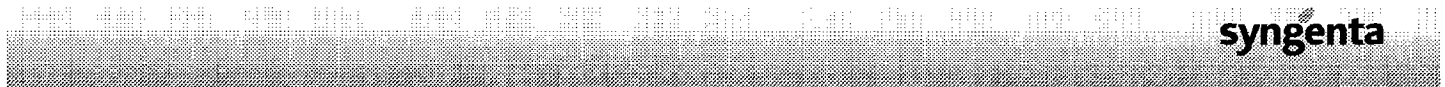
How will HSP and HA work together ?

- It will be a partnership.
- HSP will provide the 'what'.
- HA will provide the 'how'.
- However the key focus is full utilisation of all the skills and abilities within Syngenta.
- The success of HAES depends on co-operative working.



How will HSP and HA work together ?

- **HSP and HA together will provide the Health Capability for Syngenta.**
- **Management teams of HSP/HA have started working together to agree working practices.**
- **Lewis Smith, John Doe and Phil Botham (and Ian Kimber) will meet regularly to review major technical issues.**



How will Human Safety Projects and Health Assessment work together?

- **Human Safety Projects and Health Assessment together provide the Health capability for Syngenta**
- **Human Safety Project's primary purpose in HAES is to**
 - Assess the needs for health assessment
 - Design programmes to meet them within budget and time constraints
 - Integrate the results of individual studies within the overall programme
 - Give appropriate advice outside of HAES on the implications of the work
 - Assess operator and residential risk
 - Provide general expertise on products
- **Health Assessment's primary purpose in HAES is to**
 - Design studies to meet the needs of programmes
 - Perform the studies in an effective, efficient and timely way
 - Interpret the results of the studies
 - Report the studies
 - Provide specialist expertise on products and health science
- **Lewis Smith, John Doe & Phil Botham (and Ian Kimber as appropriate) will meet regularly to review major technical issues**

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How will HSP and HA work together ?

● Level 1 Products:

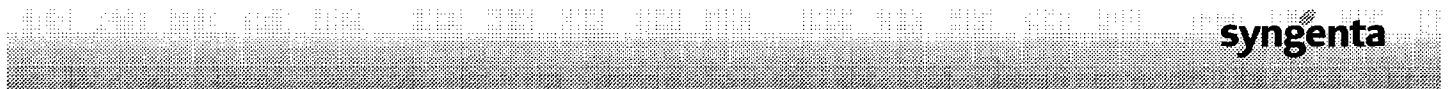
- Designated Product Toxicologist
- Team of designated experts who are expected to remain up to date on issues and who will be involved in advocacy
- HATTS where there are experimental programmes
 - Owned by John Doe
 - (Capability HATTS owned by Phil Botham)

● Level 2 Products

- Product Toxicologists working with nominated experts
- Nominated Study Reviewers point of contact for studies
- Nominated experts involved in advocacy when required

● Level 3 Products

- Product Toxicologists answering queries from existing data base
- Nominated experts rarely involved



Nominated experts to used by Product Toxicologists for Level 2 compounds

- **Toxicity Study Reviewers**
 - Oncogenicity – Paul Hext
 - Neurotoxicity – Sandra Allen
 - Safety Pharmacology – Sandra Allen
 - Crop Traits - Sandra Allen
 - Developmental Toxicology – Dick Lewis
 - Reproductive Toxicology – Dick Lewis
 - Inhalation Toxicology – Paul Hext
 - Dog Toxicology – Sandra Allen
 - General Rodent Toxicology – Dick Lewis
 - Sensitisation – Phil Botham
- **Pathology – Nicky Wallis**
- **Endocrinology – Nicky Wallis**
- **Genetic Toxicology – Barry Elliott**
- **Metabolism and pharmacokinetics**
 - Dermal Absorption – Jon Heylings
 - ADME (AP) – Brian Jones
 - ADME (BSL) - Peter Thanei
 - Kinetics – Adrian Jackson
- **Investigative Toxicology – Trevor Green**

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Human Safety Projects Operational Principles

- **Human Safety Projects Group Leaders will be accountable for achieving and maintaining the best possible qualitative toxicology position and reference doses for a coherent portfolio of products**
- **Products will be stratified into three levels based on their business category and their HAES issues and receive support from Human Safety Projects according to their level**
- **Level 1 Products will be supported by a designated team of technical experts and a HATT if there is a major experimental programme**



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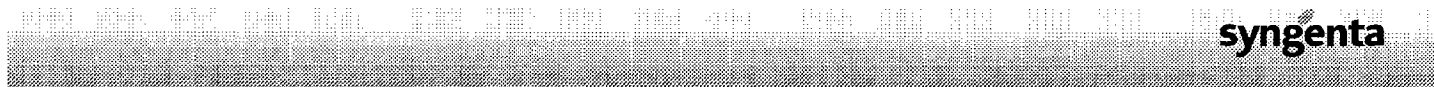
Human Safety Projects Operational Principles

- **Level 2 Products should have a named individual in Human Safety Projects accountable for them**
- **Level 3 Products will be managed in coherent portfolios**
- **The NAFTA group will primarily provide expert human safety support in NAFTA**
- **There will be one global interpretation of data with local application of these data for submissions and risk assessments**
- **The principal point of contact from outside HAES should be within a region but questions and actions should be referred to the global lead if appropriate**

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Human Safety Projects Operational Principles

- **Matrix management within Human Safety Projects should be minimised**
- **Level 1 products will be managed globally within a sector as far as possible taking into account chemical class and major business markets**
- **Level 2 products will be managed primarily on the basis of company origin of the product taking into account chemical class and major business markets**
- **Level 3 products will be managed by the European based teams on the basis of company origin**



Human Safety Projects Operational Principles

● Human Safety Project Group Leaders

- Are accountable for all of the products in their portfolio
- Will appoint Global Product Toxicologists for Level 1 and Level 2 Products in their portfolio
- Will pay particular attention to the Level 1 Products in their portfolios, they may lead HATTS, will attend such meetings as they see fit e.g. RDTs and brief senior HAES management
- May request the appointment of regional product toxicologists for regions outside of their home region if this is considered necessary
- Will be accountable for understanding and meeting the specific needs of particular regions
 - Werner Kobel – ACAP
 - Patrick Rose – EMEA
 - Dennis Hackett – NAFTA
 - Mike Clapp - LATAM

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Prioritisation of A.I.s

Blockbusters	Level 1	Experienced people in each HAES function to manage Strategic programmes & budgets for HAES & GRA
Growth with Active HAES issues		
Other Growth	Level 2	Designated product experts in each HAES function HAES/GRA programmes & budgets agreed with PDPL
Core		
Supplementary	Level 3	Designated Product experts in each HAES function Work agreed with GRA – responsive only Budget for Product Sector agreed with PDPL
Phase out		No budget or arrangements for managing

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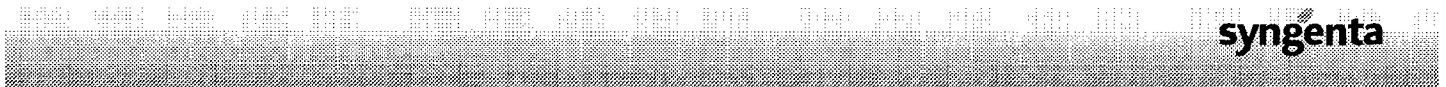
Prioritisation of A.I.s

● Level 1 A.I.s

- BB: Azoxystrobin, G: Picoxystrobin, AMS fungicide
- BB: I-cyhalothrin, Thiamethoxam, G: Abamectin(G), Emamectin benzoate, Lufenuron,
- BB: Paraquat, G: Butafenicil, Glyphosate,
- BB: Clodinafop-propargyl, Cloquintocet-mexyl, Mesotrione, s-Metolachlor, G: Atrazine, Benoxacor, Fluazifop-p-butyl, NOA 407855, Trifloxysulfuron

● Level 2 A.I.s

- Chlorothalonil, Cyprodinil, Cyproconazole, Difenaconazole, Fluazinam, Metalaxyl-M, Paclobutrazol, Penconazole, Propiconazole, Trinexapac-ethyl.
- Fenoxycarb, Methidathion, Pirimicarb, Profenofos, Pymetrozine, Tefluthrin
- Diquat
- Dicamba, Fomesafen, Molinate, Pretilachlor, Pyriftalid, Terbutylazine, Tralkoxydim, Triasulfuron



Distribution of product responsibilities in Human Safety

● Level 1 Support

→ Patrick Rose + Team

- Azoxystrobin, Picoxystrobin, AMS fungicide
- I-cyhalothrin, Thiamethoxam
- Professional Products

→ Mike Clapp + Team

- Butafenicil, Glyphosate, Paraquat,

→ Werner Kobel + Team

- Clodinafop-propargyl, Cloquintocet-mexyl, Fluazifop-p-butyl, NOA 407855
- Abamectin, Emamectin benzoate, Lufenuron,

→ Dennis Hackett + Team

- Atrazine, s-Metolachlor, Benoxacor, Trifloxysulfuron

→ Trish Malarkey + Team

- Crop Traits, Stage1, Mesotrione

→ Martin Wilks + Team

- Hypoallergenicity in carpets

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Distribution of product responsibilities in Human Safety

Level 2 A.I.s

→ Patrick Rose + Team

- Chlorothalonil, Fluazinam,
- Pirimicarb, Tefluthrin
- Tralkoxydim

→ Mike Clapp + Team

- Diquat

→ Werner Kobel + Team

- Dicamba, Oxasulfuron, Pretilachlor, Prosulfuron, Pyriftalid, Terbutylazine, Triasulfuron
- Cyproconazole, Difenaconazole, Paclobutrazol, Penconazole, Propiconazole, Cyprodinil, Metalaxyl-M, Trinexapac-ethyl
- Fenoxycarb, Methidathion, Profenofos, Pymetrozine,

→ Dennis Hackett + Team

- Fomesafen, Molinate

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